510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:
k043143

B. Purpose for Submission:
Additional features added to previously marketed device.

C. Measurand:
Device to collect for arterial blood gases

D. Type of Test:
Piston syringe (vented arterial blood sampler)

E. Applicant:
Radiometer Medical ApS

F. Proprietary and Established Names:
*safe*PICO Arterial Blood Sampler

G. Regulatory Information:
1. Regulation section:
   21 CFR§862.1675, Blood Collection Device
   21 CFR§880.5860, Piston Syringe
2. Classification:
   Class II (performance standards)
3. Product code:
   JKA, MEG
4. Panel:
   Clinical Chemistry (75)

H. Intended Use:
1. Intended use(s):
   See the indications for use below.

2. Indication(s) for use:
   "The *safe*PICO Arterial Blood Sampler is a preheparinized, electrolyte balanced, arterial blood sampler for collection of arterial samples for pH, blood gas, oximetry, electrolyte, and metabolite analyses. The *safe*PICO is a vented sampler for sample volumes in the range from 0.7 to 1.5 mL. The *safe*PICO includes a vented tip cap allowing the sampler to be vented after the appliance of the tip cap and may include a needle shield device to prevent a user from accidental needle stick."

3. Special conditions for use statement(s):
   None.

4. Special instrument requirements:
   The device can be used as a stand-alone device, although it is an integral part of the ABL900 FLEX Blood Gas Analyzer with FLEXQ module.

I. Device Description:

The *safe*PICO consists of a graduated plastic sample barrel coded with a unique barcode and a plunger. Within the sampler barrel is a soft, coated magnetic steel ball for mixing the sample before measurement and dry electrolyte-balanced lithium/sodium heparin. The sampler includes a vented tip cap that allows the sampler to be vented after the appliance of the tip cap to the male connector of the sampler. The *safe*PICO may be delivered with a conventional PVC needle cube or with a transparent plastic needle shield device connected to the needle. The needle shield consists of two axially aligned plastic tubes, each with a slit where a tab from the other may slide. Activating the thumb grip on the inner tube causes the inner tube to slide along inside the outer tube and to cover the needle point by at least 8 mm.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   PICO Arterial Blood Sampler
   PRO-VENT with NEEDLE-PRO
2. Predicate 510(k) number(s):
   k962158
   k011925
3. Comparison with predicate:
   The barrel and plunger of the *safe*PICO Arterial Blood Sampler is identical to the PICO70 Arterial Blood Sampler (k962158). Both sterile syringes have the same intended use, sample for the same analytes, have the same materials composition, and contain dried balanced heparin. The *safe*PICO adds a coated soft metal ball for mixing the sample before analysis, a pre-printed unique barcode for sample identification, a new tip cap that allows venting of the sample, and an optional protective needle shield.

K. Standard/Guidance Document Referenced (if applicable):

Area of Study	Reference Procedure	Procedure Title
Guidance	Sharps Injury Prevention Procedure	CDRH: Supplementary Guidance on Premarket Notifications for Medical Devices with Sharps Injury Prevention Features; Guidance for Industry and FDA
EO Sterilization	EN 550:1994	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization
Validation of Sterilization	ISO/CD 11135: 2001	Sterilization of health care products - Requirements of development, validation and routine control of a sterilization process for medical devices - Ethylene oxide
	EN 550:1994	Sterilization of medical devices - Validation and routine control of ethylene oxide sterilization, B.3.4.4,

Area of Study	Reference Procedure	Procedure Title
		Method C, Half-cycle method
EO Residuals	ISO10993-7:1995, # 4.3.3	Interference Testing in Clinical Chemistry
Sterilization Assurance Level (SAL)	EN 556-1:2001	Sterilisation of medical devices – Requirements for medical devices to be designated 'Sterile' - Part 1: Requirements for terminally sterilised medical devices
Sample Storage	NCCLS, H11-A4, Vol. 24 No. 28	Procedures for the Collection of Arterial Blood Specimens; Approved Standard - Fourth Edition, Section 6.6.2 Samples for Blood Gas and pH Analysis, Subsection 6.6.2.1 Prompt Analysis (within 30 minutes of collection)
Statistical Analysis of Use Study	Agresti A (2002) Categorical Data Analysis, 2nd edition, Wiley: New York.	Categorical Data Analysis
	Diggle PJ, Zeger SL, Liang K-Y (1994) Analysis of longitudinal data, Oxford University Press: New York.	Generalized Estimating Equations ("GEE")
	Zeger SL, Liang KY (1986). Biometrics. Vol. 42, pp. 121-130.	Longitudinal data analysis for discrete and continuous outcomes.

L. Test Principle:

The device is an accessory for collecting arterial blood samples. The volume drawn is pre-set by moving the plunger to the appropriate volume before puncture.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
Not applicable.

b. Linearity/assay reportable range:
Not applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):
The safePICO sampler has an estimated shelf life of 24 months (if the packaging is not compromised) based on the performance of the predicate PICO70 which has the same barrel and syringe. Real-time shelf-life studies are ongoing.

d. Detection limit:
Not applicable.

e. Analytical specificity:
Not applicable.

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

A study was designed to demonstrate equivalent recovery of the intended analytes (shown in the table below) between the *safe*PICO and the predicate PICO70 samplers. Five stock solutions with various concentrations and components were prepared in freshly drawn and centrifuged blood; another six stock solutions were made from mixtures of the original five samples. Solutions were intended to cover the analytical range of the analytes. Stock solutions were stored on ice for 20 to 30 minutes before testing. Samplers were filled from a parent syringe intended to simulate a patient draw then measured on ABL800 FLEX analyzers. Measurements were performed on three analyzers, and the experiment was repeated over three days. The discrepancy in the number of samples for each analyte is due to discarding some data points when they were found to be clearly erroneous, and some samples could not be analyzed. All measured analytes showed equivalent recovery to the predicate:

Comparison of Analyte Recovery: *safe*PICO vs. Predicate

Analyte	n =	Slope	Intercept	r =
pH	65	0.999	0.009	0.9996
pO2	59	0.985	1.028	0.9996
pCO2	65	0.995	0.199	0.9996
Chloride	65	0.999	0.122	0.9992
Calcium	64	0.997	0.002	0.9999
Potassium	59	1.004	-0.010	0.9998
Sodium	65	0.999	0.163	0.9998
Glucose	59	1.004	-0.026	0.9996
Lactate	65	0.995	0.017	0.9975
Hemoglobin (total)	65	0.998	0.343	0.9998
O2 Saturation (sO2)	59	0.9995	0.083	0.9998
Total Bilirubin	45	0.9977	-0.225	0.9998

b. Matrix comparison:

Not applicable. This device is only intended for use with arterial blood samples.

3. Clinical studies:

A simulated-use study was performed in two hospitals in Denmark, comparing the performance of the *safe*PICO and a predicate with similar safety features. Healthcare providers (n=52) experienced with arterial punctures performed multiple arterial punctures on a test fixture that simulates arterial filling of the samplers. Genders, handedness, various ages, and levels of experience were represented in the participants. Up to 10 of each kind of sampler were tested by each participant for a total of 501 tests of the safePICO and 498 tests of the predicate. The primary endpoint of the study was the number of needle stick injuries;

having no needle stick injuries was considered a successful endpoint. Secondary endpoints were successful activation of the needle shield and successful retention of the vented tip cap on the sampler during venting. Performance data was collected using a questionnaire with several parts. Objective questions were answered with a 'yes' or 'no' answer and are summarized below:

Summary of Objective Performance Evaluations: *safe*PICO vs. Predicate

	Number of counts (%) responding 'yes' to question	
Evaluation Criteria	**safePICO**	**Predicate**
NO Needle Stick Injury?	493/493 (100%)	496/496 (100%)
Safety shield activated successfully?	472/496 (95%)	494/497 (99%)
Retention of vented tip cap?	477/493 (97%)	481/496 (97%)
Able to remove needle sheath?	496/499 (99%)	179/498 (36%)
Able to complete 'arterial' sample collection?	496/499 (99%)	483/495 (98%)
Able to remove shielded needle and cover?	490/492 (99.6%)	495/497 (99.6%)

Participants were asked to respond to a series of subjective, graded questions and subjective 'yes or no' questions to compare the performance of the two samplers. Answers were: 'very easy', 'easy', 'difficult', and 'very difficult'. The percentage of respondents that answered 'very easy' or 'easy' or 'yes' for each of the questions is shown in the next table:

Summary of Subjective Performance Criteria by Study Participants: *safe*PICO vs. predicate

		Percentage of Respondents Answering 'Very Easy', 'Easy', or 'Yes"	
Item	**Evaluation Criteria**	**safePICO**	**Predicate**
1	Activating the needle shield was:	69%	96%
2	Hearing the click when the needle shield was activated was:	99%	98%
3	Knowing the needle shield was locked in place was:	98%	96%
4	Removing the shielded needle from the sampler was:	100%	94%
5	Placing the vented tip cap was:	96%	96%
6	Purging the air from the sampler was:	98%	96%
7	Overall, using this product was:	100%	62%
8	Compared to my current sampler, using this device was:	90%	56%
9	Instructions for use provide enough	94%	88%

		Percentage of Respondents Answering 'Very Easy', 'Easy', or 'Yes"	
Item	**Evaluation Criteria**	**safePICO**	**Predicate**
	training to use sampler:		
10	I was able to perform the arterial stick without changing my technique:	94%	78%
11	This device was as easy to use as a non-safety device:	94%	39%
	Items 1- 7 were graded from 'very easy' to 'very hard'		
	Items 8 – 11 were answered 'yes' or 'no'		

Thus, the *safe*PICO met the primary and secondary testing objectives; there were no needle stick injuries in the ~500 *safe*PICO samplers tested.

a. Clinical Sensitivity:
Not applicable.

b. Clinical specificity:
Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:
Not applicable.

5. Expected values/Reference range:
Not applicable.

N. Instrument Name:
*safe*PICO Arterial Blood Sampler

O. System Descriptions:

1. Modes of Operation:
Manual
2. Software:
Not applicable.
3. Specimen Identification:
Specimen can be identified by a unique barcode on the barrel of the syringe.
4. Specimen Sampling and Handling:
Instructions for use suggest that the arterial blood sample by stored at room temperature and analyzed within 30 minutes.
5. Calibration:
Not applicable.
6. Quality Control:
Sterility

P. Other Supportive Instrument Performance Characteristics Data Not Covered In the "Performance Characteristics" Section above:
Safety features on sharps should be essentially irreversible. In other words, the force needed to 'unlock' the safety feature should be much greater than the force needed to activate it. The

force needed during different phases of protective shield activation was tested on five hundred shields using an approved tensile testing bench and is summarized below:

Force required for initiating the protective shield during different parts of activation:

	Mean Force (Newton)
Starting movement of inner tube past the first retaining lock:	3.27
Force to move shield between the locks:	1.26
Force to lock shield over the needle:	8.86
Force to unlock the shield (lock on outer tube breaks):	97.97

The specifications of the Vented Tip Cap (VTC) and the results of the laboratory performance testing are shown in the table below:

Vented Tip Cap Requirement Testing

Requirement	Specification	Test Result
Ventilate sample foam w/o VTC closing too soon	Must be able to ventilate 100 uL foam	Acceptable
Air must flow through the VTC at 0.5 bar	> 100 mL/sec air through the filter	Acceptable
Max. holding pressure of the VTC before ABL800 Flex analysis	> 10 bar in 5 sec.	Acceptable
Max. holding pressure of the VTC after ABL800 Flex analysis	20 mbar	Acceptable
Penetration force of ABL800 Flex Inlet Probe	< 2.5 N	1.9
Penetration friction of ABL800 Flex Inlet Probe	< 2 N	0.8

Risk analysis and mitigation results were presented and reviewed.

The device is sterilized with ethylene oxide (EO) gas according to EN 550:1994. The sterilization assurance level (SAL) is $\leq 1x10^{-6}$ according to EN 556-1:2001.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.